K112158

MAY 10 2012

Summary of Safety and Effectiveness

Date: April 26, 2012

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
MODULUS Femoral Hip System	JDI	Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3350
	KWY	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis per 21 CFR 888.3390
	LPH	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358
	KWZ	Hip joint metal/polymer constrained cemented or uncemented prosthesis per 21 CFR 888.3310

Description:

The **Modulus femoral hip system** consists of modular femoral hip prostheses, modular CoCrMo heads, cemented UHWMPE cups (for use in total hip arthroplasty) and bipolar heads (for use in partial or hemi-hip arthroplasty).

The Modulus femoral hip prosthesis consists of a femoral stem component and a femoral neck component combined by a Morse taper locking mechanism. A locking screw is provided to improve the security of fixation. The MODULUS femoral hip prosthesis is intended for cementless use in hip joint arthroplasty.

The femoral stem has a 5° conicity with a round finned section. It is made of Ti6Al4V (ISO 5832-3, ASTM F1472) and is sandblasted. The stem is available in 11 sizes with diameters ranging from 16 to 26 mm with a 1 mm increment.

The femoral neck is available in two cervico-diaphyseal configurations (125° and 135°) and two lengths (42 and 48 mm). It is made of Ti6Al4V (ISO 5832-3, ASTM F1472). The proximal portion of the neck is highly polished while the distal portion is macro-roughened.

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Modular heads are manufactured from CoCrMo (ASTM F1537). They are characterized by a spherical shape and are used with an acetabular cup in total hip arthroplasty. The femoral heads are coupled with the MODULUS hip prosthesis by means of a 12/14 Morse taper. They are available in diameters of 28, 32 and 36 mm and in offset sizes S, M, L, XL.

Cemented cups are manufactured entirely of UHMWPE (ASTM F648, ISO 5834-2).
The acetabular cups are available in two different versions: standard and protruded. The standard version is hemispherical and is designed for use in deep acetabula. The protruded version has a lateral portion designed to resist dislocation.
An AISI 316-L stainless steel ring is inserted in the equatorial region to allow the evaluation of the device position through radiography.
The following table shows the availability of the cemented cup diameters for each type of cup.

Cup Type	Inner diameter	Range of Outer Diameter
Standard Cups	28 mm	44-58 mm with increments of 2 mm
	32 mm	50-58 mm with increments of 2 mm
Protruded Cups	28 mm	44-58 mm with increments of 2 mm
	32 mm	50-58 mm with increments of 2 mm

The Modulus femoral prostheses and modular CoCrMo heads are also compatible with the DJO FMP acetabular cups, previously cleared in K974093, K974095, K973119, K023794 and K072154.

Lock Bipolar Heads are modular prostheses characterized by an external shell made from CoCrMo (ASTM F1537) and by a conical liner made from UHMWPE (ASTM F648, ISO 5834-2). A retentive ring allows the shell to assemble with modular heads.
Lock Bipolar heads are available in 13 sizes from 45 to 57 mm with a 1 mm increment.

Intended Use: The Modulus femoral hip prosthesis is indicated for use in partial or total hip arthroplasty and is intended for press-fit (uncemented) use. When used in total hip arthroplasty, the MODULUS hip prosthesis is intended for use with a Co-Cr-Mo femoral head and a compatible acetabular cup. When used in partial hip arthroplasty, the MODULUS hip prosthesis is intended for use with a Lock Bipolar Head.

The Modulus femoral hip system is indicated for use in the following conditions:
- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- osteoarthritis after femoral heads fractures;
- correction of functional deformity;
- revisions in cases of good remaining femoral bone stock.

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The Limacorporate Cemented Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs reconstruction.

The DJO FMP acetabular cups are intended for press-fit (uncemented) use.

Predicate Devices:
Keystone Hip (Encore Medical, L.P., K000521)
PROFEMUR R femoral system (Wright Medical Technology, K041114-K091423)
WAGNER CONE stem (Centerpulse orthopaedics, K032380).
Modular Revision Hip Stem (Encore Medical, L.P., K092331)
Articul/eze femoral heads (Depuy, K883460-K980513)
PE-Plus acetabular cups (Plus Orthopaedics, K992153)
ZCA All Poly Acetabular Cup (K030153)
Global Bipolar system (Smith & Nephew, K023743)
Bipolar (Encore Orthopedics Inc. K953510)
Foundation porous coated hemispherical shell (Encore Orthopedics, Inc., K974093)
Foundation porous coated flared rim shell (Encore Orthopedics, Inc., K974095)
Foundation porous acetabular system (Encore Orthopedics, Inc., K973119)
Constrained liner (Encore Medical, L.P.,K023794)
Foundation (FMP) porous coated spiked acetabular system (Encore Medical, L.P., K072154)

Comparable Features to Predicate Devices: the Modulus femoral hip system is similar to the predicate devices in terms of intended use, indications, design and materials.

The Modulus femoral prosthesis and the predicate femoral prostheses are indicated for use in hip arthroplasty and for press-fit (uncemented) use. The CoCrMo heads and the predicate heads are all indicated for use in total hip arthroplasty, while the Lock Bipolar heads and the predicate bipolar heads are all indicated for use in partial hip arthroplasty. The cemented cups and the predicate acetabular cups are intended for cemented use in hip arthroplasty where the acetabular socket needs reconstruction.

Like the Keystone Hip, the Profemur R femoral system and the Modular Revision Hip system, the Modulus femoral prosthesis is a modular prosthesis made up of a cylindrical stem and a proximal body that are joined through a taper connection stabilized by a safety screw. As with the predicates devices, the Modulus prosthesis is characterized by a 12/14 neck-head taper. The cemented cups and the predicate cups are all monolithic and are characterized by several grooves in the outer surface to enhance fixation and rotational stability of the cup in bone cement. Like the Global Bipolar System, the Lock Bipolar heads are modular devices composed of an external shell, an inner liner and a locking mechanism.

The components of the Modulus femoral hip system are manufactured from the same materials as the predicate devices.

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Non-Clinical Testing: The Modulus femoral hip system has undergone fatigue testing to demonstrate the strength of the femoral stem and the strength of the modular connections. A pull-out test was performed to test the force necessary to disassemble the Lock bipolar head. A simulation of the Range of Motion has been performed to ensure the device design does not overly limit range of motion. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. The testing results demonstrated the system's ability to perform under expected clinical conditions.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the Modulus femoral hip system to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

LimaCorporate S.p.A.
% Ms. Cheryl Hastings
Principal Consultant
P.O. Box 696
Winona Lake, Indiana 46590

MAY 10 2012

Re: K112158
Trade/Device Name: Modulus stems, necks, heads, and cups
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI, KWY, KWZ
Dated: March 30, 2012
Received: April 4, 2012

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): ~~Unknown~~ K112158

Device Name: MODULUS Femoral Hip System

Indications for Use:

MODULUS Femoral Hip System
Indications for Use

The MODULUS stems are indicated for use in partial or total hip arthroplasty and are intended for press-fit (uncemented) use. When used in total hip arthroplasty, the Modulus Stems are intended for use with Co-Cr-Mo femoral heads and a compatible acetabular cup. When used in partial hip arthroplasty, the Modulus Stems are intended for use with the Lock Bipolar Heads.

Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis and hip dysplasia;
- rheumatoid arthritis;
- osteoarthritis after femoral heads fractures;
- correction of functional deformity;
- revisions in cases of good remaining femoral bone stock.

The Limacorporate Cemented Cup is intended for cemented use in hip arthroplasty where the acetabular socket needs reconstruction.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112158